



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

je

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,035	06/25/2003	Clarence Nathaniel Ahlem	202.2D4	6394
<div>26551 7590 09/13/2007 HOLLIS-EDEN PHARMACEUTICALS, INC. 4435 EASTGATE MALL SUITE 400 SAN DIEGO, CA 92121</div>				
			EXAMINER BADIO, BARBARA P	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 09/13/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/607,035

Applicant(s)

AHLEM ET AL.

Examiner

Barbara P. Badio, Ph.D.

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 50 and 54-84 is/are pending in the application.
- 4a) Of the above claim(s) 56, 60, 65 and 68-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 50, 54, 55, 57-59, 61-64, 66, 67 and 77-84 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Final Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 50 and 54-84 are pending in the present application. Claims 56, 60, 65 and 68-76 stand withdrawn from further consideration as being drawn to a nonelected invention. Claims 50, 54, 55, 57-59, 61-64, 66, 67 and 77-84 will be examined to the extent they read on the elected species according to MPEP § 803.02.

Election/Restrictions

3. For the record, it is noted that the instant claims recite compounds outside the scope of genus that will be examined in the present application, i.e., compounds wherein R⁸ is -O- or -NH- and/or R⁹ is -CHR¹⁰-CHR¹⁰-.

Specification

4. **The objection to the specification is maintained.**

According to applicant, the nature of the remaining objections for pages 89, 137, 211 and 239 are unclear. As stated in the previous Office Action, said pages have data/text missing. For example, page 89, section 000217, the heading reads, "intermit

Art Unit: 1617

nt d sing m thuds". The same problem exists on pages 137, 211 and 239 of the present specification.

For this reason and that given in the previous Office Action, the objection to the specification is maintained.

Claim Objections

5. The objection to claims 66 and 67 under 37 CFR 1.75(c), as being of improper dependent form is withdrawn.

6. The provisional rejections of the instant claims over copending Application Nos. 10/607,415 and 10/949,694 as discussed in the previous Office Action is maintained.

It is noted in the reply filed April 24, 2006, applicant stated that said provisional rejection be held in abeyance. The examiner assumes said is still applicant's intention.

Claim Rejections - 35 USC § 103

7. The rejection of claims 50, 54, 55, 57-59, 61-64, 66, 67 and 77-84 under 35 USC 103(a) over Dowell et al. (US 5,859,000) is maintained.

Applicant argues (a) piecemeal examination of the present invention based on the citing of the '000 patent; (b) examination normally proceeds beginning with the elected species which was omitted by the obviousness analysis; (c) hindsight bias and (d) failure to establish a prima facie case because the '000 patent (i) encompassed a

Art Unit: 1617

vast array of compounds and the Office has not provided a rationale for a person skilled in the art to prepare the compound in Applicant's elected species or any other species in the instant claims and (ii) teaches away for the treatment of asthma outside of a mast cell mediated allergic reaction. Applicant's argument was considered but not persuasive for the following reasons.

First, in response to applicant's objection to the citation of the '000 patent because it was previously considered by the examiner as evidenced by the IDS dated June 15, 2005 (considered by the examiner October 12, 2005), it is noted that there is no time limit as to when references cited by applicant on a IDS may be cited against the claimed invention. Additionally, the examiner saw no reason(s) to enter a new ground of rejection citing another piece of prior art in the Final Office Action dated October 21, 2005 because said action contained a rejection under 35 USC 103(a) that was maintained from the First Office Action dated February 4, 2005.

The examiner notes applicant's request that the present Office Action be made nonfinal because the '000 was not previously applied. However, as indicated above, the time of citation of the above-mentioned patent is not considered improper and, thus, the examiner finds no reason to accord applicant additional time by making the instant action nonfinal.

Secondly, applicant argues the rejection should be withdrawn because (a) examination should begin with the elected species and the obviousness analysis omits said species, (b) hindsight reconstruction of the claimed invention was employed and (c) the examiner fail to establish a prima facie case of obviousness.

In response to applicant's argument as to the merit of the rejection, the examiner notes:

(a) The elected species was utilized as a starting point for examination as is evidenced by all of the previous Office Actions. That is, in the present application, search of the Markush claims was based on steroids having oxygen attached to the 3, 16 and 17 positions irrespective of stereochemistry. Said search was inclusive of hydroxyl, ester and ether groups as encompassed by the instant claims. Again, as stated in previous Offices, examination was according to MPEP § 803.02.

(b) In the previous Office Action, the examiner notes compounds exemplified by the reference having a 17-hydroxy group and a 3-ether or a 16-hydroxyl group. Said compounds provide guidance to the skilled artisan to obtain the claimed elected species. As stated in the previous Office Action, the skilled artisan needs only make substitution of one group taught by the reference for another also taught by the reference in order to obtain the instantly claimed compounds, including applicant's elected species. Based on the teachings of the cited reference, the skilled artisan would have the reasonable expectation of predictable results, i.e., utilization of said compound(s) obtained by making the stated substitution(s) in treatment of asthma as taught by the reference. Said modification is not hindsight because the reference teaches making said substitution(s) as well as provide the motivation to make said substitution. Again as stated in the previous Office Action, the motivation is based on the fact that the reference teaches equivalence of said groups in these positions and the utilization of the compounds for treatment of asthma. Applicant has not provided any

Art Unit: 1617

reason(s) why said substitution would be unobvious, i.e., would not result in the results taught by the reference.

(c) As stated in (b), the reference provides the necessary motivation to make the claimed compounds and, thus, a prima facie case of obviousness is made.

Lastly, applicant argues the scope of compounds taught by the reference and the lack of teaching for the treatment of asthma of every etiology. It is noted that the instant invention (a) encompasses a vast number of compounds including heterocyclic compounds and (b) lacks teaching of the utilization of the claimed compounds in treating asthma of based on etiology. However, the issue is not the scope of the prior art compounds or the underlining cause of the asthma. The issue is whether the claimed invention would have been obvious to one of ordinary skill in the art at the time of the present invention based on the teachings of the prior art, i.e., whether the cited prior art makes obvious the utilization of the claimed compound(s) for treating asthma. The examiner maintains that said is obvious based on the cited reference and, thus, the instant claims are prima facie obvious based on the teachings of the cited reference.

For these reasons and those given in the previous Office Action, the rejection of claims 50, 54, 55, 57-59, 61-64, 66, 67 and 77-84 under 35 USC 103(a) over Dowell et al. (US 5,859,000) is maintained.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

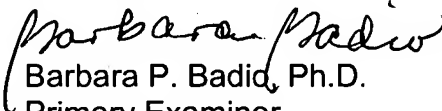
Telephone Inquiry

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Barbara P. Badiu, Ph.D.
Primary Examiner
Art Unit 1617

BB

September 10, 2007